DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Baltimore District Office
Central Region
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04-BLT-08

December 9, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Nash, M.D.
Medical Director
Laboratory Services
Southside Community Hospital
800 Oak Street
Farmville, Virginia 23901-1199

Dear Dr. Nash,

The Food and Drug Administration (FDA) conducted an inspection at your unlicensed blood bank facility located at 800 Oak Street, Farmville, VA, on October 14-16, 2003. The inspection revealed numerous deviations from the Current Good Manufacturing Practice (cGMP) regulations for Blood and Blood Components, Title 21, Code of Federal Regulations (CFR), Part 606. These deviations cause your blood products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations documented on the Form FDA-483 issued and discussed with you at the conclusion of the inspection included:

1. Failure to maintain records concurrently with the performance of each significant step in the collection of each unit of blood and blood components so that all steps can be clearly traced [21 CFR 606.160(a)(1)]. Specifically,

a. your firm failed to document the destruction of recoverd plasma on the Autologous Checklist form for units [redacted] and as required.
b. your firm failed to initial and date the of the foil pouch for [redacted] Blood – Pack units, lot numbers [redacted] and [redacted] causing the [redacted] Blood – Pack units to be used beyond the manufacturer's expiration date; and
c. your firm failed to document the signature of the phlebotomist or the witness on the Autologous Checklist form for unit [redacted] as required

2. Failure to maintain equipment used in the storage of blood and blood products in a clean and orderly manner [21 CFR 606.60(a)], in that the refrigerator used for storing RBC units contained

low temperature mold growth in the container of temperature probe solution and on the interior walls of the refrigerator.

3. The container label fails to include the expiration date, including the day, month [21 CFR 121(c)(4)]. Specifically, the autologous RBC units for [redacted], [redacted], and failed to include the expiration date on the unit label.

4. Failure to follow written standard operating procedures (SOP) including all steps to be followed in the distribution of blood and blood components for autologous transfusion [21 CFR 606.1 00(b). Specifically, RBC autologous unit [redacted] was not disposed of on the expiration date of the unit, as required by SOP entitled, [redacted].

5. Failure to use supplies and reagents in a manner consistent with instructions provided by the - [21 CFR 606.65(e)], in that [redacted], lots of Blood-Pack units (lot numbers [redacted] and [redacted] in foil pouches, were open and exposed to air for an undetermined period of time, against manufacturer's instructions.

6. The standard operating procedure (SOP) fails to include written descriptions of solutions and methods used to prepare the site of phlebotomy to give maximum assurance of a sterile container of blood [21 CFR 606.100(b)(3)], in that your firm does not have a written SOP for the [redacted] method used for arm preparation.

7. The standard operating procedure (SOP) fails to include a written description of schedules and procedures for equipment maintenance and calibration [21 CFR 606.100(b)(15)], in that there is no written cleaning schedule or procedure for the refrigerator used to store blood and blood products.

8. Appropriate records are not available to determine the lot numbers of supplies used for specific units of the final product [21 CFR 606.160(a)(2)]. Specifically, the Autologous Checklist form for units [redacted] and [redacted] do not have lot numbers for the [redacted] Blood-Pack units recorded.

9. The standard operating procedure (SOP) fails to include a written description of the storage temperature and methods of controlling storage temperatures for all blood products and reagents [21 CFR 606.100(b)(10)]. Specifically, the SOP entitled [redacted] of [redacted] does not include a method for verifying the temperature of incoming blood units is within the required range.

The above deficiencies are not intended to be an all-inclusive list of deficiencies at your blood bank facility. Several of these deficiencies were cited on a Form FDA 483 or discussed with managers at your facility during previous inspections. It is your responsibility to ensure that your blood bank facility is in compliance with all applicable requirements of 21 CFR Part 606 and the Act.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by FDA without further notice. Such action includes seizure and/or injunction.

FDA acknowledges receipt of your undated response letter to the inspectional observations, which was received in our office on November 21, 2003. We have reviewed your response and found it to be inadequate for the following reasons:

1. Your revised standard operating procedures (SOPs) do not include the initials and date of the person(s) who reviewed and approved the new procedures.
2. Your firm submitted no documentation indicating that employees have been trained in the revised procedures. Documentation should include a training sheet/log with the employee's name, signature, date of training, name of trainer, and the subject of the training.
3. In reference to procedures that will now be reviewed/monitored by the Lab Director, it should be stated in your revised SOPs that the Lab Director will review the document/form/procedure within a specified timeframe and where that review will be documented.
4. Your corrective action for Observation #6 is inadequate in that your firm's SOP entitled [redacted] does not include the length of time used on the scrub with the [redacted] and the length of time to wait after the scrub for the area to dry.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. Your response should address the comments listed above and include examples of documentation showing 'that corrections have been achieved. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Vinetta Howard-King, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21228. If you have any questions, please do not hesitate to contact Ms. Howard-King at (410) 779-5454, extension 413.

Sincerely,
/s/
Kirk Sooter for Lee Bowers
Director, Baltimore District